

Applicants: Marc Feldmann and Ravinder N. Maini  
Serial No.: 09/921,937  
Filed: August 3, 2001  
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required if two or more independent and distinct inventions are claimed in one application. Under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden.

The inventions of groups I-VIII are not independent. Under M.P.E.P. §802.01, "independent" means there is no disclosed relationship between the subject matter claimed. The inventions of groups I-VIII relate to methods of treating or preventing a tumor necrosis factor-mediated disease in an individual in need thereof comprising co-administering methotrexate and a TNF $\alpha$  antagonist to said individual, in therapeutically effective amounts. Applicants therefore maintain that the inventions of groups I-VIII are not independent and restriction is not proper.

Furthermore, under M.P.E.P. §803, the Examiner must examine the application on the merits if examination can be made without serious burden, even if the application would include claims to distinct or independent inventions. That is, there are two criteria for a proper requirement for restriction: (1) the invention must be independent and distinct, and (2) there must be a serious burden on the Examiner if restriction is not required.

Applicants respectfully submit that there would not be a serious burden on the Examiner if restriction were not required, because a search of the prior art relevant to the non-elected groups would not require a serious burden once the prior art relevant to the elected group has been identified.

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Therefore, there would be no serious burden on the Examiner to examine groups I-VIII together in the subject application. Hence, the Examiner must examine these groups on the merits.

In view of the foregoing, applicants maintain that restriction is not proper under 35 U.S.C. §121 and respectfully request that the Examiner reconsider and withdraw the requirement for restriction.

### **Sequence Compliance**

On page 2 of the August 26, 2003 Office Action, the Examiner alleged that the subject application fails to comply with the requirements of 37 C.F.R. §§1.821-1.825 for the reason(s) set forth on the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures. Applicants attach hereto a copy of the Notice as **Exhibit A**.

The Notice to Comply With Requirements for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures indicates that neither a paper copy of the Sequence Listing nor a copy of the Sequence Listing in computer readable form (CRF) has been submitted as required by 37 C.F.R. §1.821(e).

In response, applicants submit herewith (a) a paper copy of a Sequence Listing, attached hereto as **Exhibit B**, and inserted into the specification following the Abstract of the Disclosure, (b) a request to use the CRF of the sequence listing submitted in connection with prior application U.S. Serial No. 08/690,775, filed September 17, 1999, now U.S. Patent No. 6,270,766, issued August 7,

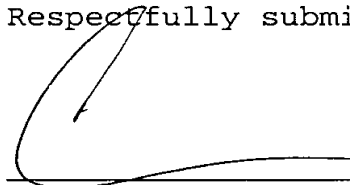
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2001, attached hereto as **Exhibit C** and (c) a statement in accordance with 37 C.F.R. §1.821(f) attached hereto as **Exhibit D**, certifying that the CRF submitted in the prior application and the written sequence listing contain the same sequence information.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, other than the enclosed \$110.00 extension fee, is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Alan J. Morrison  
Reg. No. 37,399

10/27/03  
Date